UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,839	06/23/2000	Markus Pompejus	BGI-127CP	9461

959 7590 02/13/2003

LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER
LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
1634	13

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/602,839	Applicant(s) POMPEJUS ET AL.	
	Examiner Frank W Lu	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 36-39* is/are pending in the application.

4a) Of the above claim(s) *17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 36-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on November 11, 2002 has been entered as Paper No:11. The claims pending in this application are claims 1-17 and 36-39.

Election/Restriction

2. Applicant's election with traverse of Group I, claims 1-4 and 9-16 and SEQ ID NO: 1 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that: (1) "[G]roups I-V, Group XIII, Group XIII, and at least claim 17 of Group VI, should be regrouped together into a single Group containing claims 1-17 and 36-38 ('new Group I')." since "the isolated nucleic acid molecules, vectors, and host cells of Groups I-V, XII and XIII, and the claimed methods of making a polypeptide of claim 17, are related. There is a disclosed relationship between the claimed inventions of Groups I-V, XII, XIII, and the methods of claim 17."; (2) " [T]he nucleic acid molecule of claims 1-4, 5, 6, 7, and 8 (Groups I-V) are clearly all related as they are all portions of or variants of the same nucleotide sequences,"; (2) "[S]ince claims 1-17 and 36-38 encompass the same isolated nucleic acid molecules and products, a search of the isolated nucleic acids of Groups I-V, XII and XIII and the method of claim 17 would be co-extensive and would not involve a serious burden on the Examiner."; (3) "Groups I-V are included in the same class and subclass."; (4) "the U.S. Patent and Trademark Office has routinely grouped claims directed to nucleotides, variants of the same nucleotide sequences, and fragments of the same nucleotide sequences together in a single Group. Furthermore, the U. S. Patent and Trademark Office has

routinely grouped claims directed to host cells which comprise specific nucleotide sequences together in a single Group with claims directed to the same nucleotide sequences."; (4) "[A]pplicants respectfully request that at least 10 sequences be examined in the instant application" since "the policy set forth in 1192 O.G. 68 (Nov. 19, 1996), clearly provides that a reasonable number of sequences are allowed to be claimed in a single application" and "up to ten independent and distinct sequences are often examined in a single application without restriction"; and (5) "it is the Applicants' position that, with respect to the claimed nucleotide sequences, a species election for searching purposes would be more appropriate in this situation.".

After carefully considering applicant's arguments, the examiner agrees to combine Groups I-V, XII and XIII (claims 1-16 and 36-38) and examine these groups together. However, the above arguments have not been found persuasive toward the withdrawal of all restriction requirements nor persuasive toward the relaxation of same such that Groups I-V, XII, and XIII (claims 1-16 and 36-38) and claim 17 (part of Group VI) will "be regrouped together into a single Group containing claims 1-17 and 36-38 ('new Group I') and at least 10 sequences will be examined together. First, the examiner agrees with applicant "the isolated nucleic acid molecules, vectors, and host cells of Groups I-V, XII and XIII, and the claimed methods of making a polypeptide of claim 17, are related.". However, there will be a search burden on the Examiner because a search of the isolated nucleic acids of Groups I-V, XII and XIII will not involve to search a method of producing a polypeptide as recited in claim 17. Furthermore, as shown in previous office action, the product as claimed in Groups I-V, XII and XIII can be used in a materially different process of using that product such as the method in Group IX and Groups I-

V, XII and XIII ("new Group I") and Group IV have different classifications. Second, in previous office action, the examiner clearly indicated that SEQ ID Nos. in this instant application should not to be construed as a species election. Since SEQ ID NO: 2 is the protein sequence of SEQ ID NO: 1, the examiner agrees to search SEQ ID Nos: 1 and 2 together. Third, the examiner agrees with applicant, according to the policy set forth in 1192 O.G. 68 (Nov. 19, 1996), "up to ten independent and distinct sequences are often examined in a single application without restriction". However, the phrase "up to ten" does not mean that the examiner must examine ten independent and distinct sequences. Since nucleic acids comprising SEQ ID NOS: 1, 3, 5, 11, 13, 15, 17, 19, 21, and 23 encode different proteins (SEQ ID NO: 2, 4, 6, 12, 14, 16, 18, 20, 22 ,and 24), these SEQ ID NOS are considered to be structurally distinct chemical compounds and are unrelated to one another. MPEP 803.04 states that "[N]ucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.".

Therefore, the requirement is still deemed proper and is therefore made FINAL and claims 1-16 and 36-39 will be examined.

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

4. Claims 1, 3, 5-7, and 36-39 are objected to because of the following informality: the phrase "SEQ ID NO: 3, SEQ ID NO: 5, SEQ ID NO: 11, SEQ ID NO: 13, SEQ ID NO: 15, SEQ ID NO: 17, SEQ ID NO: 19, SEQ ID NO: 21, or SEQ ID NO: 23 " should be deleted and replace with "SEQ ID NO:1" since applicant has selected SEQ ID NO: 1 as the result of the restriction requirement.

5. Claim 2 is objected to because of the following informality: Note that "SES" is an abbreviation. This phrase can only be used after it appears once.

6. Claims 4, 5, and 39 are objected to because of the following informality: the phrase " SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 12, SEQ ID NO: 14, SEQ ID NO: 16, SEQ ID NO: 18, SEQ ID NO: 20, SEQ ID NO: 22, or SEQ ID NO: 24" should be deleted and replace with "SEQ ID NO:2" since applicant has selected SEQ ID NO: 1 as the result of the restriction requirement and the examiner only agrees to examine SEQ ID NO: 2 (see above Response to Argument of Restriction).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-6, 9-16, and 36-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is referred to the interim guidelines on written description published on December 21, 1999 in the Federal Register at Volume 64, Number 244, pp.71427-71440.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116.

The specification (pages 1-75, Table 1 and Sequencing listing) provides adequate written description for isolated nucleic acid molecule consisting of the nucleotide sequence of SEQ ID No: 1 and its corresponding protein sequence (SEQ ID NO:2), which serves as a protein

translation elongation factor. However, the specification fails to adequately describe: (1) any kind of isolated nucleic acid molecule comprising the nucleotide sequence of or set forth in SEQ ID NO: 1, a vector comprising said nucleic acid molecule, and a host cell comprising said nucleic acid molecule as recited in claims 1-3, 9-16, and 39; (2) any kind of isolated nucleic acid molecule which encodes a polypeptide comprising the amino acid sequence of or set forth in SEQ ID NO: 2 as recited in claims 4 and 39; (3) any kind of isolated nucleic acid molecule which encodes a naturally occurring allelic variant of a *Corynebacterium glutamicum* polypeptide comprising the amino acid sequence of or set forth in SEQ ID NO: 2 wherein the nucleic acid molecule can hybridize to the complement of a nucleic acid molecule consisting of SEQ ID NO: 1 in 6X SSC at 45 ^{0}C as recited in claims 5 and 39; (4) any kind of isolated nucleic acid molecule comprising the nucleotide sequence which has at least 50% identity with the nucleotide sequence of SEQ ID No: 1 as recited in claims 6 and 39; (5) any kind of isolated nucleic acid comprising a fragment of at least 15 nucleotides of the nucleotide sequence of SEQ ID NO: 1 as recited in claims 7 and 39; (6) a host cell comprising the nucleic acid molecule of SEQ ID NO: 1 wherein the nucleic acid molecule is disrupted as recited in claim 36; (7) a host cell comprising the nucleic acid molecule of SEQ ID NO: 1 wherein the nucleic acid molecule comprises one or more nucleic acid modifications as recited in claim 37; and (8) a host cell comprising the nucleic acid molecule of SEQ ID NO: 1 wherein the regulatory region of the nucleic acid molecule is modified relative to the wild-type regulatory region of the molecule as recited in claim 38. The claimed inventions as a whole are not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of

Applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed inventions as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998).

In this instant case, an isolated nucleic acid molecule recited in claims 1-3 and 9-16, and (a) of claim 39 was read as any kind of isolated nucleic acid molecule which had SEQ ID NO: 1 and was longer than the nucleotide sequence consisting of SEQ ID NO: 1, and could be read as a chromosome having SEQ ID NO: 1. An isolated nucleic acid molecule recited in claim 4 and (c) of claim 39 was read as any kind of isolated nucleic acid molecule which had SEQ ID NO: 1 and was longer than the nucleotide sequence consisting of SEQ ID NO: 1 and could be read as a chromosome having SEQ ID NO: 1 since this nucleic acid molecule could encode a polypeptide comprising the amino acid sequence of or set forth in SEQ ID NO: 2. An isolated nucleic acid molecule recited in claim 5 and (d) of claim 39 was read as any kind of naturally occurring allelic variant of a nucleic acid molecule which had SEQ ID NO: 1 and was longer than the nucleotide sequence consisting of SEQ ID NO: 1 wherein the isolated nucleic acid molecule could hybridize to the complement of a nucleic acid molecule consisting of SEQ ID NO: 1 in 6X SSC at 45 ^{0}C. An isolated nucleic acid molecule recited in claim 6 and (e) of claim 39 was read as any kind of nucleic acid which has at least 50% identity with the nucleotide sequence comprising SEQ ID No: 1 that had SEQ ID NO: 1 and was longer than the nucleotide sequence consisting of SEQ ID NO: 1. An isolated nucleic acid molecule recited in claim 7 and (f) of claim 39 was read as any

kind of isolated nucleic acid comprising a fragment of at least 15 nucleotides of the nucleotide sequence of SEQ ID NO: 1 and could be read as a chromosome having at least 15 nucleotides of SEQ ID NO: 1. A host cell recited in claim 36 was read as a host cell comprising any kind of nucleic acid molecule because claim 36 did not limit the extent, percentage, and location of the disruption and the nucleic acid molecule with the disruption was not considered as the same nucleic acid molecule which had SEQ ID NO: 1 and was longer than the nucleotide sequence consisting of SEQ ID NO: 1. A host cell recited in claim 37 was read as a host cell comprising any kind of nucleic acid molecule because claim 37 did not limit the extent, percentage, and location of the modification and the nucleic acid molecule comprising more nucleic acid modifications as recited in claim 37 was not considered to be the same nucleic acid molecule which had SEQ ID NO: 1 and was longer than the nucleotide sequence consisting of SEQ ID NO: 1. A host cell recited in claim 38 was read as a host cell comprising any kind of nucleic acid molecule because claim 38 did not limit the extent, percentage and location of the modification and the nucleic acid molecule comprising the modifications on the regulatory region as recited in claim 38 was not considered to be the same nucleic acid molecule which had SEQ ID NO: 1 and was longer than the nucleotide sequence consisting of SEQ ID NO: 1. Although the specification adequately describes an isolated nucleic acid consisting of the nucleotide sequence of SEQ ID No: 1 and its corresponding protein sequence (SEQ ID NO: 2), claims 1-7, 9-16, and 36-39 encompass numerous unknown and unidentified nucleic acids that have polynucleotide sequence adding to 5', 3' and/or within the nucleotide sequence of SEQ ID No. 1 or nucleic acids encoding various variants of SEQ ID No. 1 that miss from the disclosure. It is unclear whether these

variants of SEQ ID No: 1 can still serve as a protein translation elongation factor as SEQ ID NO: 1 does. Therefore, the general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed.

With limited disclosure provided by the specification, the skilled artisan cannot envision all the possible variant nucleic acid sequences which would be homologous or hybridize but do not correspond to nucleotide sequence consisting of SEQ ID No: 1, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method used. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co.* Ltd., 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated nucleic acid molecule consisting of SEQ ID No: 1 and its corresponding protein sequence consisting of SEQ ID NO: 2 meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

9. Claims 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for modulating in production of certain kind of fine chemical using a nucleic acid molecule consisting of SEQ ID NO: 1, does not reasonably provide enablement for modulating in production of any kind of fine chemical recited in claims 15 and 16 in any kind of cell using a nucleic acid molecule comprising or consisting of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 1, 2, and 10-14 were not included in the rejection since these claims are directed to a nucleic acid molecule, a vector comprising the nucleic acid molecule, and a host cell comprising the nucleic acid molecule which are enabling in view of the specification.

In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

Claims 15 and 16 are drawn to a host cell having a nucleic acid comprising SEQ ID NO: 1 wherein a nucleic acid comprsing SEQ ID NO: 1 is capable of modulating in production of any kind of fine chemical recited in claims 15 and 16 in any kind of cell. The specification describes

that a nucleic acid consisting of SEQ ID NO: 1 can modulate in production of a fine chemical selected from claim 16 (pages 9-23). However, the specification does not provide any evidence to show how a nucleic acid comprising or consisting of SEQ ID NO: 1 (protein translation elongation factor G, see Table 1) can modulate in production of any one of fine chemicals selected from claim 16 in any kind of cells. The evidence from an art search appears against the claimed invention as recited in claims 15 and 16. First, since it was well known in the art that protein synthesis in eucaryotes (ie., animal cells) and procaryotes (i.e. bacteria cells) required different ribosome subunits (see Text book of Biochemistry with Clinical correlations, edited by Thomas Devlin, third edition, 1992, page 725-727, specifically see Table 17.1), it is unclear whether a nucleic acid comprising or consisting of SEQ ID NO: 1, a protein translation elongation factor G from *Corynebacterium glutamicum* (see Table 1), can interact with ribosome subunits from an eukaryote and modulate in production of any one of fine chemicals recited in claims 15 and 16 in an eukaryotic cell. Second, since conserved nucleotide sequences of the protein translation elongation factor G among bacteria were 41-85% (Caldon *et al.,* Molecular microbiology, 41, 289-297, 2001, see Table 1), it is unclear whether a nucleic acid comprising or consisting of SEQ ID NO: 1 (protein translation elongation factor G from *Corynebacterium glutamicum*) can function in any kind of bacteria strain to modulate in production of any one of fine chemicals recited in claims 15 and 16. Third, it was known that disruption of certain kind of protein translation elongation factor in certain kind of cell did not affect survival of the cell. For example, disruption of ELF1 (an elongation like factor) in *Candida albicans* produced a mixture of large, irregular cells and apparently normal cells wherein the disrupted strains grew more slowly than

wild-type (Sturtevant *et al.*, Microbiology, 144, 2311-2321, see abstract) and disruption of GTPBP1 (elongation factor 1 α) in mice did not affect functions of antigen-present cells (Senju et al., Mol. Cell. Biol., 20, 6195-6200, 2000, see abstract). These evidence suggested that other protein translation elongation factor(s) can at least partially replace functions of the disrupted elongation factor and a protein translation elongation factor can not modulate in production of any kind of fine chemicals in a cell. Without an evidence in the specification, it is unclear whether a nucleic acid comprising or consisting of SEQ ID NO: 1 (protein translation elongation factor G from *Corynebacterium glutamicum* see Table 1) can modulate in production of any kind of fine chemicals recited in claims 15 and 16 in a cell. With these unpredictable factors, the skilled artisan will have no way to predict the experimental results.

Thus, in view of the lack of guidance, working examples, breadth of the claims, the level of skill in the art and state of the art at the time of the claimed invention was made, it would have required undue experimentation to make and/or use the invention as claimed. These undue experimentation at least includes to test whether a nucleic acid molecule comprsing or consisting of SEQ ID NO: 1 can modulate in production of any kind of fine chemical recited in claims 15 and 16 in any kind of cells.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 36 is rejected as vague and indefinite becuase it is unclear whether the disrupted nucleic acid molecule can be still called as SEQ ID No. 1 since the claim does not limit the extent and percentage of the disruption. Please clarify.

13. Claim 37 is rejected as vague and indefinite becuase it is unclear the nucleic acids with more modifications can be still called as SEQ ID No. 1 since the claim does not limit the extent and percentage of the modifications. Please clarify.

14. Claim 38 is rejected as vague and indefinite becuase it is unclear the nucleic acids with modifications on its regulatory region can be still called as SEQ ID No. 1 since the claim does not limit the extent and percentage of the modifications and it was known that the regulatory region of a nucleic acid molecule can locate anywhere of a genomic DNA. Please clarify.

Claim Rejections - 35 U.S.C. § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.839

16. Claims 1, 3, 6-9 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by New England Biolabs (1996/1997 Catalog, pages 113, 114, 164, and 165).

Regarding claims 1, 3, 6, 7, and 39, #1079 of the Catalog of New England Biolabs disclosed the linker of restriction enzyme ApaI with nucleotides 5'-GGGGCCCC-3' (page 113). Since nucleotides 50-57 of SEQ ID NO: 1 was CCCCGGTA (5' to 3'), the linker of restriction enzyme ApaI was considered as a complement of SEQ ID No: 1 as recited in claims 1 and 3, and a) and (b) of claim 39, a complement of an isolated nucleic acid molecule comprising a nucleotide sequence which has at least 50% identity of SEQ ID NO: 1 as recited in claim 6 and (e) of claim 39, and a complement of an isolated nucleic acid molecule comprising a fragment of at least 15 nucleotide of SEQ ID NO: 1 as recited in claim 7 and (f) of claim 39 becuase it had a portion of SEQ ID No: 1. Note that SEQ ID NO: 1 was at least 50% identity (100%) of SEQ ID NO: 1.

Regarding claim 8, the linker of restriction enzyme ApaI (5'-GGGGCCCC-3') was capable of hybridizing with nucleotides 50-57 of SEQ ID NO: 1 (5'-CCCCGGTA-3) with 75% base match. Since the specification defines "under stringent conditions" as "conditions for hybridization and washing under which nucleotide sequences at least 60% homologous to each other typically remain hybridized to each other (see page 34, lines 3-8), the linker of restriction enzyme ApaI (5'-GGGGCCCC-3') was considered to be capable of hybridizing with nucleotides 50-57 of SEQ ID NO: 1 (5'-CCCCGGTA-3) under stringent conditions.

Regarding claim 9, pMal vector comprised a polylinker and a lacZα gene (see page 165). Since a nucleotide connected with the first nucleotide of 5' lacZα gene in the polylinker and the lacZα gene were considered as a portion of SEQ ID NO: 1 and a nucleotide sequence encoding a heterologous polypeptide respectively, the pMal vector was considered to comprise a portion of SEQ ID NO: 1 and a nucleotide sequence encoding a heterologous polypeptide recited in claim 9.

Therefore, New England Biolabs (1996/1997 Catalog, pages 113 and 114) teaches all limitations recited in claims 1, 3, 6-9, and 39.

Conclusion

17. No claim is allowed.

18. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
February 6, 2003

Ethan Whisenant, Ph. D.
Primary Examiner (FSA)